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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/074,620 | 02/13/2002 | Pamela A. Green | | 7365 |

7590 04/08/2003

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EXAMINER

LI, BAO Q

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1648 | 8 |

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/074,620 | GREEN ET AL. |
| | Examiner Bao Qun Li | Art Unit 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 January 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, drawn to a composition or primer for detecting Epstein-Bar (EB) virus, classified in class 424, subclass XXX.

Upon election of Group I, Applicant is additionally required to elect one pair of primer sequences selected from (a0 SEQ ID NO: 1 and 2 or (b) SQ ID NO: 5-6 to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each pair of primer is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.
 - II. Claim 6, drawn to a method of detecting the presence of EB virus DNA in the sample comprising contacting the sample with a hybridization probe, classified in class 435, subclass X.

Upon election of Group II, Applicant is additionally required to elect one single probe sequence to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each probe is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.
 - III. Claims 7-25, drawn to another method for amplification of the EB virus with a pair of primers, and further contacting the sample with one hybridization probe, classified in class 435, subclass X.
 - IV. Claims 26-30, drawn to a method of selecting an appropriate dosage or type of antiviral agent for treating an infection caused by EB virus, classified in class XX, subclass X.
 - V. Claims 31-32, drawn to a method for the simultaneously amplification and detection of EB virus DNA in sample, classified in class XX, subclass X.
 - VI. Claims 33-39, drawn to a kit for detecting EB virus, classified in class X, subclass X.

Upon election of Group III-VI, Applicant is additionally required to one pair of primer from (a) SEQ ID NO: 1 and 2 or (b) SEQ ID NO: 5 and 6, and elect one single probe sequence selected from Group consisting of SEQ ID NO: 3, 4, 7 and 8 to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each probe is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

3. Species A: (1). PCR, (2). LCR, (3). SDA, (4). Q β RA, (5). 3SR, and (6). NASBA.
4. Species B: (i). Thermostable polymerase, (ii). E. coli DNA pol I, (iii). Klenow fragment, (iv). T4 DNA polymerase.
5. Species C : a). digoxigenin-dUTP, b). biotin, c). calorimetric, d). fluorescent, e). chemiluminescent, f). electrochemiluminescent signal, g). a radioactive component.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 9, 26 and 33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 1648

6. The inventions are distinct, each from the other because:
7. Inventions of groups II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods, which use different modes, e.g. the method of Group II is directed a method of detecting the presence of EB virus DNA in the sample comprising contacting the sample with one hybridization probe, whereas the method of group III is directed to another method for amplification of the EB virus with a pair of primers, and further contacting the sample with one hybridization probe.
8. Inventions group I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as an antibody or antigen detection, rather using a primer to do the PCR reaction .
9. Because these inventions are distinct for the reasons given above , the restriction for examination purposes as indicated is proper.
10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

April 4, 2003

James C. Housel
JAMES HOUSEL 4/7/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600